NIH grant application process from submission to completion with focus on NIAID methods grants.

Johns Hopkins University
Bloomberg Scholl of Public Health

November 1, 2013
Baltimore, Maryland
Outline

- National Institutes of Health
- Pre-submission to submission
- Grant Submission
- Grant review and funding approval
- NIH new policies
- Global Health
- Resources and contacts
National Institutes of Health

- NIH has 27 institutes and centers, each with its own research focus. See where your research might fit.

- Institutes (21)
  - Disease specific Institutes (20).
    - E.g. NIAID, NCI, NHLBI, …
  - General biomedical research
    - National Institute of General Medical Sciences (NIGMS).

- Centers (6)
  - Fogarty International Center.
    - International (Global health) research and training activities
  - Center for Scientific Review.
    - Grant submission and review
Pre-submission to Submission

- Is your research related to NIH’s mission?
- NIH Mission:
  - To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
  - [http://www.nih.gov/about/mission.htm](http://www.nih.gov/about/mission.htm)

- Is your proposal disease specific?

- Ex. NIAID (missions, strategic planning)
  - [http://www.niaid.nih.gov/about/whoweare/Pages/default.aspx](http://www.niaid.nih.gov/about/whoweare/Pages/default.aspx)
Selected Topics from NIAID Statistical Methods Portfolio

- Statistical methods for evaluating vaccine efficacy.
- Mathematical and experimental models for HIV dynamics.
- Data-driven computational modeling of the growth and spread of viruses.
- Nonparametric modeling of long-term HIV/Immune Cell dynamics.
Pre-submission to Submission

- Preparing for Grant submission
  - Investigator-initiated
    - General: [Parent Program Announcements](http://www.niaid.nih.gov/researchfunding/ann/pages/opps.aspx)
    - Initiatives: Program Announcements (PAs)
  - Solicited research
    - Request for Applications (RFAs)

- NIAID Pas and RFAs

- Subscribe (weekly updates):
  - [http://www.niaid.nih.gov/ncn/newsletters/default_subscribe.htm](http://www.niaid.nih.gov/ncn/newsletters/default_subscribe.htm)

- Glimpse future initiatives (Concepts).
Select grant mechanism, make sure the relevant NIH institution accepts that mechanism

- R: research grants
- P: research program project (multidisciplinary)
- K: research career development
- F: research fellowships
- T: research training grants

http://grants.nih.gov/grants/funding/funding_program.htm
Pre-submission to Submission (Small grants Vs R01)

- **R03** limited funding for short period of time (pilot or feasibility studies, collection of preliminary data, secondary analysis of existing data…)

- **R21** is useful if you don’t have preliminary data and feel you are not yet competitive with other R01 applicants. Encourages new, exploratory and development research project.

- However, if you have preliminary data that can support your research hypothesis, you should go straight for the **R01** (Research project grant).
Pre-submission to Submission (Grant mechanism contd...)

- NIH Pathway to Independence (K99/R00) award Must be within 5 years of terminal degree. Work towards preparing an R01 application
  - Phase I: mentored support, 1-2 years fellowship (K99).
  - Phase II: Independent research, up to 3 years (R00).

- R21/R33 Exploratory developmental grant (check IC)
  - R21: provides support for early and conceptual stages of project development.
  - R33: Provides support for promising project started at the R21 phase.
Pre-submission to Submission

• If you are not ready for independent support:
  • become part of someone else's grant or
  • apply for a training or career award.

- Ex. Career Development (K25): Mentored quantitative research development award
  • Supports junior faculty-level investigators with quantitative scientific and engineering backgrounds outside of biology or medicine who have the potential to integrate their expertise with biomedicine and develop into productive investigators with a period of mentored study and research.
Pre-submission to Submission (Sample proposals and abstracts.)

- R01 Sample proposals and summary statements, NIAID

- K 25 Sample proposals, NHLBI
  - [http://www.nhlbi.nih.gov/funding/training/redbook/k25models.htm](http://www.nhlbi.nih.gov/funding/training/redbook/k25models.htm)

- NIH Funded grant abstracts (project reporter)
  - [http://projectreporter.nih.gov/reporter.cfm](http://projectreporter.nih.gov/reporter.cfm)
# Submission Dates (Eg. R01 grant mechanism)

<table>
<thead>
<tr>
<th></th>
<th>Cycle I AIDS/Others</th>
<th>Cycle II AIDS/Others</th>
<th>Cycle III AIDS/Others</th>
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<tbody>
<tr>
<td>Submission date</td>
<td>May 7/ March 5</td>
<td>September7/ June 5</td>
<td>January 7/ October 5</td>
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<tr>
<td>Scientific Merit Review</td>
<td>June - July</td>
<td>October - November</td>
<td>February - March</td>
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<tr>
<td>Advisory Council Review</td>
<td>September - October</td>
<td>January - February</td>
<td>May - June</td>
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<tr>
<td>Earliest Project Start Date</td>
<td>December</td>
<td>April</td>
<td>July</td>
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Grant Submission

- Center for Scientific Review: Handles the receipt and review of NIH grant applications.
  - Assigns applications to a funding institute and to a Study Section for review
  - Cover letter: Institute assignment and study section assignment can be requested. CSR will try to accommodate the request if appropriate and possible.
  - Scientific Review Officer (SRO): CSR contact for applicants after submission and prior to the review meeting.

- Study sections
- [http://public.csr.nih.gov/StudySections/Standing/Pages/default.aspx](http://public.csr.nih.gov/StudySections/Standing/Pages/default.aspx)
Grant Submission
(Ex. Methods Study sections)

- Biostatistical Methods and Research Design (BMRD)
- AIDS Clinical Studies and Epidemiology (ACE); statistical methods relevant to HIV research.
- Modeling and Analysis of Biological Systems (MABS; modeling complex biological systems)
1st Level Review

- Scientific Merit: Reviewed by Study Section Members (20-30 scientific experts).

- Reviewers for Statistical methods application (3-4 scientific experts) if assigned to
  - BMRD all most all methods reviewers
  - Subject area study section (one or two subject matter reviewer)
1\textsuperscript{st} Level Peer Review (Scientific Merit)

- **Significance** – importance of problem.
  - If the aims of the project are achieved how will scientific knowledge be improved?

- **Investigator(s)** – training, experience
  - Are Program Director, Principal investigator(s) and collaborators well suited to the project?

- **Innovation** - novelty of approach
  - Does the application challenge and seek to shift current research by using novel approaches or methodologies?
1st Level Peer Review contd. (Scientific Merit)

- **Approach – concept, methods**
  - Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

- **Environment – Institutional support**
  - Will the scientific environment contribute to the probability of success?
## Priority Scores

<table>
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<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
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<tbody>
<tr>
<td><strong>High Impact</strong></td>
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<tr>
<td>1</td>
<td>Exceptional</td>
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<td>2</td>
<td>Outstanding</td>
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<tr>
<td>3</td>
<td>Excellent</td>
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<td><strong>Moderate Impact</strong></td>
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<td>4</td>
<td>Very Good</td>
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<td>5</td>
<td>Good</td>
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<td>Satisfactory</td>
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<td><strong>Low Impact</strong></td>
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<td>8</td>
<td>Marginal</td>
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<tr>
<td>9</td>
<td>Poor</td>
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Scoring System

- This scale will be used for scoring overall impact AND individual criterion
  - Significance, Investigators, Innovation, Environment, Approach (individual scores given only by reviewers and discussants)
  - Overall impact score will not be weighted average of individual scores (given by entire committee)

- If application discussed: Applicant will get both individual criterion and overall impact score

- If application not discussed: Applicant will get individual criterion scores only
Most common Reasons for proposal to be not-highly-meritorious

- Lack of new or original ideas,
- Unfocused Research Plan,
- Lack of knowledge of Published relevant work,
- Uncertainty concerning the future directions,
- Unrealistically large amount of work,
- Lack of experience/expertise in the biology*,
- Not readable to clinicians*.

*common reasons on statistical methods grants.
Pay line is set for each fiscal year depending on the budget approved by congress and the number of applications received.

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Pay line (percentile)</th>
<th>New PIs</th>
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<tbody>
<tr>
<td>2003</td>
<td>22</td>
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<tr>
<td>2004</td>
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<td>2005</td>
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<tr>
<td>2006</td>
<td>14</td>
<td>16</td>
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<td>2007-2008</td>
<td>12</td>
<td>14</td>
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<tr>
<td>2009</td>
<td>12</td>
<td>25</td>
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<td>2011-12</td>
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<td>14</td>
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<td>2013</td>
<td>8</td>
<td>12</td>
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<tr>
<td>2014 (interim)</td>
<td>6</td>
<td>10</td>
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Review

- **1st Level Peer Review, Scientific Merit**
  - Study Sections: Scientific experts (3-4 reviewers, statistical methods grants, at least one subject matter reviewer).

- **2nd Level Peer review: Funding recommendation**
  - National Advisory Council: Scientific experts, Division Directors and Advocacy organization representatives.
What determines which awards are funded?

- Scientific Merit (Study section result).
- Program and/or Policy considerations
- Availability of funds
Application not in a fundable range

- Read summary statement carefully. Talk to your Program Officer (PO).
- If reviewers concern is fixable then revise and resubmit
- If concern is not fixable then re-evaluate
  - If substantial change needed then submit a new application
Special NIH policies for new investigators

Goals

- Encourage transition to independence for investigators
- Counter trend of increasing time spent in training phase of career
- Strongly encourage New Investigators (NIs), particularly Early Stage Investigators (ESIs), to apply for R01 grants when seeking first-time NIH funding
New Investigator (NI) Designation

- Someone who has never successfully competed for a “significant” NIH award as a PI.
- Examples of awards you could have successfully competed for: R03, R15, R21, F awards, K awards, L awards.
- There is no limit as to how old you are or how long you have been out of school.
Early Stage Investigator (ESI)

- An ESI is a New Investigator (NI) who is within 10 years of completing his/her terminal research degree or medical residency (or the equivalent).

- To ensure appropriate consideration for ESI eligibility, all NIs will need to update their eRA Commons profiles, and will now see their eligibility displayed in eRA Commons.
Special Considerations for ESI’s

- Applications from ESIs will be given special consideration during peer review and at the time of funding.

- Peer reviewers will focus more on the investigator’s experience and training rather than the record of accomplishments that have advanced their chosen field.

- Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator.
Special NIH Policy for Multiple PI

- **Goal**
  - Encourage team science
  - Recognize contributions of collaborators
  - Align NIH policy with other federal agencies
Multiple PI core Principles

- The presence of more than one PI does not diminish the responsibility or accountability of any PI.

- The decision to apply with more than one PI is the responsibility of the investigators and the applicant institution.

- Multiple-PI does not imply more than one project.
Multiple PI Application
Points to Consider

- PI roles
  - The science determines the level of effort, no minimum level
  - One PI serves as contact person, communicate with NIH coordinating yearly progress report,
  - All PIs have the same status and responsible for their projects

- New Investigator status: All investigators must be new investigators
Multiple PI Application
Points to Consider

- Leadership Plan
  - Rationale and justification for choosing multiple PI approach
  - Administrative and scientific responsibilities for each PI
  - Governance and organizational structure of the team
  - Procedures for resolving conflicts
  - Policies for communication, data sharing, publication and intellectual property
  - Budget issues
Global Health Research and Training

- **Fogarty International Center (FIC)**
  - Part of NIH dedicated to advancing the mission of NIH by supporting and facilitating global health research conducted by US and international investigators.
  - [http://www.fic.nih.gov/Funding/Pages/default.aspx](http://www.fic.nih.gov/Funding/Pages/default.aspx)

- **NIAID Research Grant (R01)** applications from eligible foreign countries that propose research related to infectious diseases that are of interest to that country (can be collaborative).
Resources and Contacts

- Office of Extramural research: All about grants
  - [http://grants.nih.gov/grants/oer.htm](http://grants.nih.gov/grants/oer.htm)

- Center for Scientific Review
  - [http://public.csr.nih.gov/aboutcsr/Pages/default.aspx](http://public.csr.nih.gov/aboutcsr/Pages/default.aspx)

- NIAID’s Tutorial on grant process and funding

- Fogarty International Center
Resources and Contacts

- Investigators in your institutions who have funded NIH grants
- CSR contact: Scientific Review Officer
- Program Contact:
  - NIAID statistical methods grants contact
  - Misrak Gezmu, mgezmu@niaid.nih.gov
- Other Institutes Program contact:
  - Check specific institute website.
- Thank you